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(71) Applicant: **SCIMED LIFE SYSTEM, INC.** [US/US]; One Scimed Place, Maple Grove, MN 55311 (US).

(72) Inventor: **COUVILLO, Lucien, Alfred, Jr.**; 190 Nashawtuc Road, Concord, MA 01742 (US).

(74) Agents: **BONHAM, David, B.** et al.; Mayer Fortkort & Williams, PC, 251 North Avenue West, 2nd Floor, Westfield, NJ 07090 (US).

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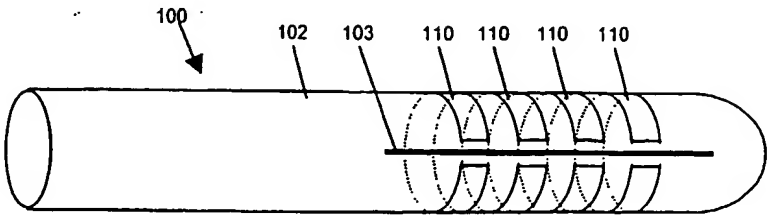
(54) Title: ELECTRONICALLY ACTIVATED CAPTURE DEVICE



(57) Abstract: A novel capture device apparatus comprising: (a) a capture device portion, at least a part of which is adaptable for isertion into a patient and (b) a control unit. The capture device portion comprises one or more apertures and one or more electroactive polymer actuators that open and close the one or more apertures based on control signals sent fron the control unit. In another aspect of the present invention, a method of capturing a specimen within a patient's body of provided. The method comprises (a) providing a capture device apparatus like that above, (b) inserting at least a portion of the capture device portion of the apparatus into the patient such that the capture device portion is adjacent the specimen; and (c) closing the one or more aperture using the control unit, thereby capturing the specimen.

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member, (b) a counter-electrode and (c) a region comprising an electrolyte disposed between the active member and the counter-electrode. In preferred embodiments, the one or more electroactive polymer actuators further comprise a substrate layer and a barrier layer, with the active member, counter-electrode and the region comprising the electrolyte being disposed between the substrate layer and barrier layer. Preferred electroactive polymers for the practice of the present invention include polyaniline, polypyrrole, polysulfone and polyacetylene.

[0007] The one or more apertures within the device capture portion can be mechanically biased, for example, toward either an open position or a closed position.

[0008] In some embodiments, the one or more apertures are closed upon contraction of the one or more actuators and opened upon expansion of the one or more actuators. Conversely, in other embodiments, the one or more apertures are opened upon contraction of the one or more actuators and closed upon expansion of the one or more actuators.

[0009] In still other embodiments, the one or more apertures are (a) opened upon expansion of a first set of one or more actuators and contraction of a second set of one or more actuators, and (b) closed upon contraction of the first set of actuators and expansion of the second set of actuators.

[0010] In some embodiments, the control unit can simply comprise a power source and a switch. In others, the control unit can be more complex, comprising, for example, a computer. The control unit can be coupled to the one or more actuators in a number of ways, for example, via an electrical cable or wireless interface.

[0011] According to another aspect of the present invention, a method of capturing a specimen within a patient's body is provided. The method comprises (a) providing a capture device apparatus like that above, (b) inserting at least a portion of the capture device portion of the apparatus into the patient such that the capture device portion is adjacent the specimen; and (c) closing the one or more apertures using the control unit, thereby capturing the specimen.

[0012] In some embodiments, at least one aperture within the capture device portion is lined by one or more blades, allowing the specimen to be severed using the blades. In other embodiments, a vacuum is provided within the device capture portion to draw the specimen into the one or more apertures, assisting capture of the specimen.

[0013] The capture device apparatus can be inserted, for example, into a body lumen

[0024] Figs. 7C and 7D are cross-sectional views of the distal end of a capture device in accordance with another embodiment the present invention, in closed and open positions, respectively;

[0025] Figs. 8A and 8B are schematic perspective views of the outer jacket portion of the distal end of a capture device like that of Figs. 7A and 7B, in which apertures associated with the outer jacket are illustrated in closed and open positions, respectively;

[0026] Fig. 9A is a schematic perspective view of a structural element for use in a capture device, in accordance with an embodiment of the present invention;

[0027] Fig. 9B is a schematic perspective view of a substrate layer with attached electroactive polymer actuators, in accordance with an embodiment of the present invention;

[0028] Fig. 9C is a schematic perspective view of the structural element of Fig. 9A upon being wrapped in the substrate layer of Fig. 9B, in accordance with an embodiment of the present invention;

[0029] Figs. 10A-10C are schematic cross sectional views illustrating actuator configurations, in accordance with three embodiments of the present invention;

[0030] Figs. 11A-11C are schematic perspective views of capture device apparatuses, in accordance with three embodiments of the present invention.

DETAILED DESCRIPTION OF THE INVENTION

[0031] The present invention now will be described more fully hereinafter with reference to the accompanying drawings, in which preferred embodiments of the present invention are shown. This invention may, however, be embodied in different forms and should not be construed as limited to the embodiments set forth herein.

[0032] According to preferred embodiments of the present invention, capture devices for insertion into the body of a patient are provided, which contain one or more electroactive polymer actuators. The devices of the present invention can be used to capture a wide array of specimens within the body, for example, emboli, polyps (including polyps of the respiratory tract, cervix and colon), stones (including stones of the liver, gallbladder, and urinary tract), and various biopsy specimens. Patients include vertebrate patients, especially human patients.

[0033] Actuators based on electroactive polymers, members of a family of plastics

provided by electrolyte 14, which adjoins member 12 over at least a portion, and up to the entirety, of the surface of active member 12 in order to allow for the flow of ions between the two media. Many geometries are available for the relative disposition of member 12 and electrolyte 14. In accordance with preferred embodiments of the invention, member 12 may be a film, a fiber or a group of fibers, or a combination of multiple films and fibers disposed so as to act in consort for applying a tensile force in a longitudinal direction substantially along axis 11. The fibers may be bundled or distributed within the electrolyte 14.

[0039] Active member 12 includes an electroactive polymer. Many electroactive polymers having desirable tensile properties are known to persons skilled in the art. In accordance with preferred embodiments of the invention, active member 12 is a polypyrrole film. Such a polypyrrole film may be synthesized by electrodeposition according to the method described by M. Yamaura et al., "Enhancement of Electrical Conductivity of Polypyrrole Film by Stretching: Counter-ion Effect," Synthetic Metals, vol. 36, pp.209-224 (1988), which is incorporated herein by reference. In addition to polypyrrole, any conducting polymer that exhibits contractile or expansile properties may be used within the scope of the invention. Polyaniline is an example of such a usable conducting polymer.

[0040] Electrolyte 14 may be, for example, a liquid, a gel, or a solid, so long as ion movement is allowed. Moreover, where the electrolyte 14 is a solid, it should move with the active member 12 and should not be subject to delamination. Where the electrolyte 14 is a gel, it may be, for example, an agar or polymethylmethacrylate (PMMA) gel containing a salt dopant. Where the electrolyte is a liquid, it may be, for example, a phosphate buffer solution. The electrolyte is preferably non-toxic in the event that a leak occurs *in vivo*.

[0041] Counter-electrode 18 is in electrical contact with electrolyte 14 in order to provide a return path for charge to a source 20 of potential difference between member 12 and electrolyte 14. Counter-electrode 18 may be any electrical conductor, for example, another conducting polymer, a conducting polymer gel, or a metal such as gold or platinum, which can be applied by electroplating, chemical deposition, or printing, for example. In order to activate actuator 10, a current is passed between active member 12 and counter-electrode 18, inducing contraction or expansion of member 12. Additionally,

this example, the actuators are wrapped around the tubular structural element 102. The aperture 103 remains closed so long as the actuators 110 are in an expanded state.

[0048] Referring now to Fig. 2B, once the actuators 110 are placed in a contracted state, the aperture 103 in the elastic structural element 102 opens. Once opened, the resultant "mouth" can be used to engulf numerous objects within the body, including polyps, stones, and emboli, as well as various other blockages or specimens. Subsequently, when the actuators 110 are once again placed in an extended state, the aperture 103 returns to the configuration of a slit (due, for example, to the elastic restoring force inherent in structural element 102), capturing the object of interest.

[0049] Of course, numerous flexible tubular structural elements are known besides the structural element 102 of Figs. 2A and 2B. For example, rather than being provided in the shape of a solid tube (notwithstanding the aperture), the structural element can be formed using a non-solid flexible tube. Exemplary non-solid flexible tubes include tubular open-mesh networks comprising one or more knitted, woven or braided filaments as well as flexible perforated tubes (e.g., laser-cut tubes). Preferred materials for the tubular structure element 102 are polymeric materials, metallic materials and combinations thereof. For example, a polymeric material reinforced with a braided wire tube, axial stiffening members, or a perforated tube can be used. Reinforced structures of this type are common, for instance, in the guide catheter art.

[0050] Where the capture devices of the present invention are employed in operations requiring a cutting step (for example, in the removal of gastrointestinal polyps), it may be desirable to provide the aperture with a cutting edge. For example, it may be possible to sharpen the material defining the edges of the aperture, for instance, where the material is a metal or a hard plastic material. Alternatively, as illustrated in Fig. 3, the aperture can be provided with blades 107 of flexible metal material. Suitable blades include blades of the type presently used in connection with Boston Scientific's Cutting Balloon™ Device (for more information, see, e.g., http://www.bostonscientific.com).

[0051] In the above embodiments, the actuators are wrapped around a portion of the circumference of the tubular structural element 102. However, numerous additional configurations are possible. For example, referring now to Fig. 4, a capture device 100 is illustrated containing elastic tubular structural element 102 with aperture 103. Four

components are otherwise axially movable relative to one another, upon the expansion of actuators 110a and the contraction of actuators 110b, the jacket 104 buckles in the region outside of actuators 110b as illustrated in Fig. 7B.

[0057] The effect of buckling the outer jacket 104 can be better seen in Figs. 8A and 8B. Due to presence of slits 103 in jacket 104 (see Fig. 8A), upon buckling of the jacket, the slits 103 widen, forming capture apertures (see Fig. 8B).

[0058] Hence, in the capture device of Figs. 7A-B, opening and closing forces are exerted by two sets of opposing actuators. This eliminates the need for an inherent mechanical bias to provide the necessary force to open or close the device. The same is true for the device of Figs. 7C-D immediately below.

[0059] A variation of the design of Figs. 7A-B is illustrated in Figs. 7C-D. Referring now to Fig. 7C, there is illustrated a cross-sectional view of the distal end of a capture device 100, which includes a stiff inner tubular member 106 and a flexible outer jacket 104. Actuators 110a are attached to the jacket 104, while actuators 110b are attached to both the jacket 104 and the stiff tubular member 106, via adhesive regions 119.

[0060] In the configuration illustrated in Fig. 7C, actuators 110a are in an expanded state, while actuators 110b are in a contracted state. Upon contraction of actuators 110a and expansion of actuators 110b as illustrated in Fig. 7D, the jacket 104 buckles in the region outside of actuators 110a in a manner similar to the above.

[0061] In general, the orientation of the aperture(s) in the capture devices of the present invention can be inferred from the intrinsic position-dependent electrical properties of the electroactive polymer actuators therein. However, strain gauges can be employed to provide electronic feedback concerning the orientation of the actuators and openings within the assembly, if desired. This electronic feedback will also provide a number of additional advantages, including greater stability, error correction, and immunity from drift. Electronic feedback also permits a haptic interface to the controller, in which the operator may "feel" the force fed back. Strain gauges suitable for use in the present invention include (a) feedback electroactive polymer elements whose impedance or resistance varies as a function of the amount of strain in the device and (b) conventional strain gauges in which the resistance of the device varies as a function of the amount of strain in the device, thus allowing the amount of strain to be readily quantified and monitored. Such strain gauges are commercially available from a number of different

aperture 103, while expansion of the actuator elements 110 results in closure of aperture 103.

[0066] It is noted that the device of Figs. 9A-9C uses actuator contraction to open the aperture of the device, while relying on the inherent bias of the structural element to effect device closure. However, if desired, additional actuators can be provided, for example, along the lines of the device of Figs. 5A-5B, to provide a device in which both closing and opening forces are exerted by two sets of actuators in opposition with one another. In this case, the need for an inherent bias within the structural element to effect device closure is eliminated.

[0067] Although Figs. 9A-9C illustrate a single substrate layer 105, multiple substrate layers can be used. As one example, an additional substrate layer can be provided which contains strain gauges, such as feedback polymer elements, along with a readout bus for transmitting information from the strain gauges to a controlling device. As another example, multiple actuator layers can be employed.

[0068] Actuators 110 can be provided on substrate layer 105 in numerous configurations. For example, a single actuator 110 is shown in cross-section in Fig. 10A, disposed on substrate layer 105. As previously discussed, the actuator 110 includes an active member 112 as a first electrode along with a counter-electrode 118, with an intervening electrolyte-containing layer 114.

[0069] The substrate layer 105 is formed of a flexible material. Electrically insulating materials are preferred. Flexible materials useful in the construction of the substrate layer 105 include the following polymeric materials: polyolefins such as metallocene catalyzed polyethylenes, polypropylenes, and polybutylenes and copolymers thereof; ethylenic polymers such as polystyrene; ethylenic copolymers such as ethylene vinyl acetate (EVA), butadiene-styrene copolymers and copolymers of ethylene with acrylic acid or methacrylic acid; polyacetals; chloropolymers such as polyvinylchloride (PVC); fluoropolymers such as polytetrafluoroethylene (PTFE); polyesters such as polyethylene terephthalate (PET); polyester-ethers; polysulfones; polyamides such as nylon 6 and nylon 6,6; polyamide ethers such as polyether block amides; polyethers; elastomers such as elastomeric polyurethanes and polyurethane copolymers; silicones; polycarbonates; polychloroprene; nitrile rubber; butyl rubber; polysulfide rubber; *cis*-1,4-

112, on the other hand, are provided with discrete track wires (not shown), allowing for individual or concerted activation, as desired.

[0077] As another example, Fig. 10C is a cross-section including five active members 112 and four counter-electrode regions 118 disposed on a substrate layer 105. An electrolyte-containing layer 114 contacts both the active members 112 and counter-electrode regions 118. A barrier layer 120 is sealed to the substrate layer 105 using, for example, an adhesive 119. The active members 112 are provided with discrete track wires (not shown), allowing individual or concerted activation, as desired. The counter-electrode regions 118 can also be provided with discrete track wires (not shown), or these regions can constitute parts of a single counter-electrode.

[0078] As previously noted, substrate layer 105 is formed from an insulating material in many preferred embodiments. However, where the active elements are to be simultaneously actuated, then the substrate layer 105 can be formed form a conductive material, for example, a metal such as gold or platinum. In this instance, the substrate can be used as a current path, eliminating the need for independent track wires.

[0079] Fig. 11A is a simplified schematic diagram of a capture device apparatus in accordance with an embodiment of the invention. The capture device apparatus includes a capture device portion 100 containing an aperture 103 and various electronic actuators (not shown), which are controlled by a controlling device 154. An electrical cable 150 is provided between the capture device portion 100 and controlling device 154.

[0080] A wide range of controlling devices can be used with the present invention. For example, the controlling device can simply consist of a switch and a power source, such as a battery. Alternatively, the controlling device can be significantly more sophisticated, which is desirable, for example, where individual actuator control is required. As a specific example, a computer provided with an electronic interface (including drivers) can be employed as a controlling device 154. In this instance, signals are sent from drivers in the electronic interface associated with the personal computer 154, through cable bundle 150, to the actuators within capture device portion 100, to open and close the capture device portion 100 as needed.

[0081] As noted above, in some embodiments of the invention, the capture device

within the teaching of the present invention, which is to be limited only by the claims appended hereto.

7. The capture device apparatus of claim 1, wherein said one or more apertures within said device capture portion are mechanically biased toward an open position.

8. The capture device apparatus of claim 1, wherein said one or more apertures within said device capture portion are mechanically biased toward a closed position.

9. The capture device apparatus of claim 1, wherein said one or more apertures are closed upon contraction of said one or more actuators and opened upon expansion of said one or more actuators.

10. The capture device apparatus of claim 1, wherein said one or more apertures are opened upon contraction of said one or more actuators and closed upon expansion of said one or more actuators.

11. The capture device apparatus of claim 1,

wherein said one or more apertures are opened upon expansion of a first set of said one or more actuators and contraction of a second set of said one or more actuators, and

wherein said one or more apertures are closed upon contraction of said first set and expansion of said second set.

12. The capture device apparatus of claim 1, wherein at least one of said one or more apertures is lined by one or more blades.

13. The capture device apparatus of claim 1, further comprising a vacuum pump coupled to at least one of said one or more apertures.

14. The capture device apparatus of claim 1, wherein said control unit comprises a power source and a switch.

15. The capture device apparatus of claim 1, wherein said control unit comprises a computer.

24. The method of claim 23, wherein said polyp is a sessile polyp.

25. The method of claim 23, wherein said polyp is a pedunculated polyp.

26. The method of claim 18, wherein said specimen is a stone.

27. The method of claim 18, wherein said specimen is an embolus.

28. The method of claim 18, wherein said specimen is a biopsy specimen.

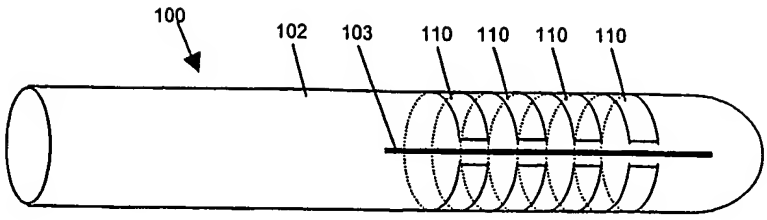

Fig. 2A

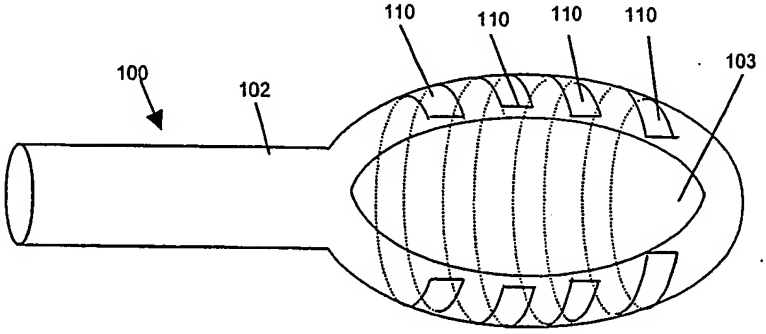

Fig. 2B

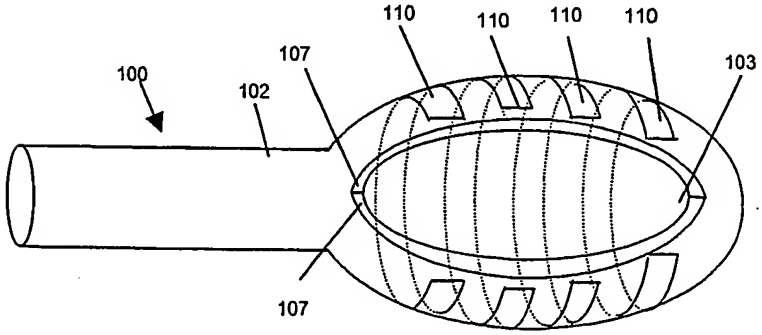

Fig. 3

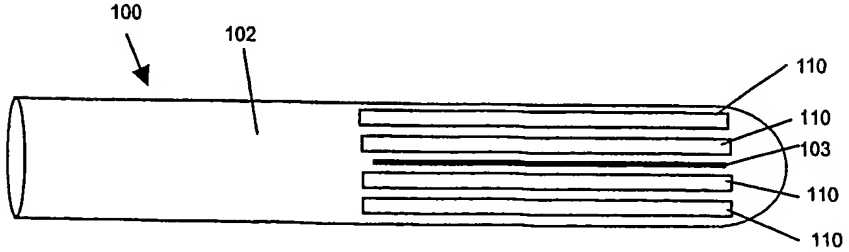

Fig. 4

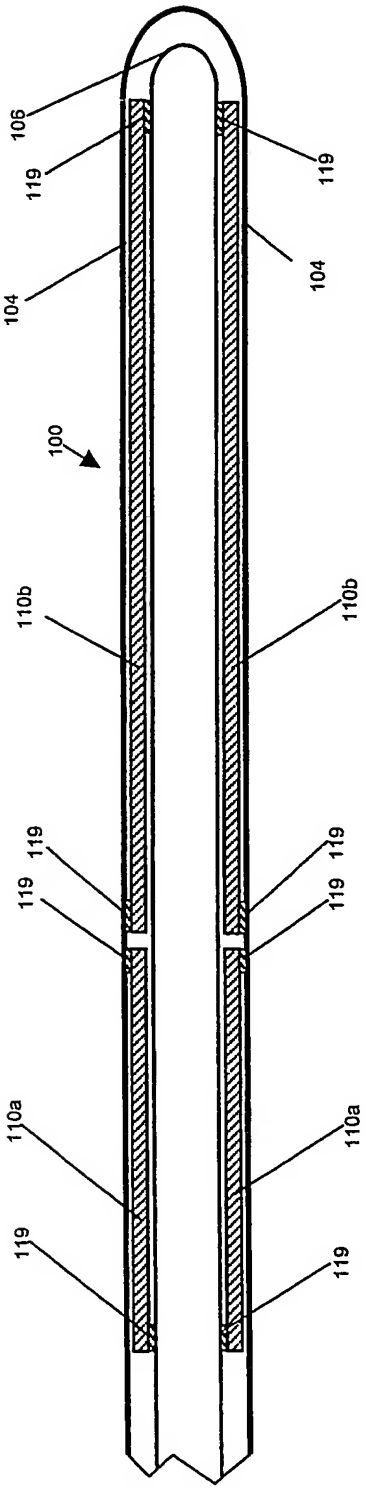

Fig. 7A

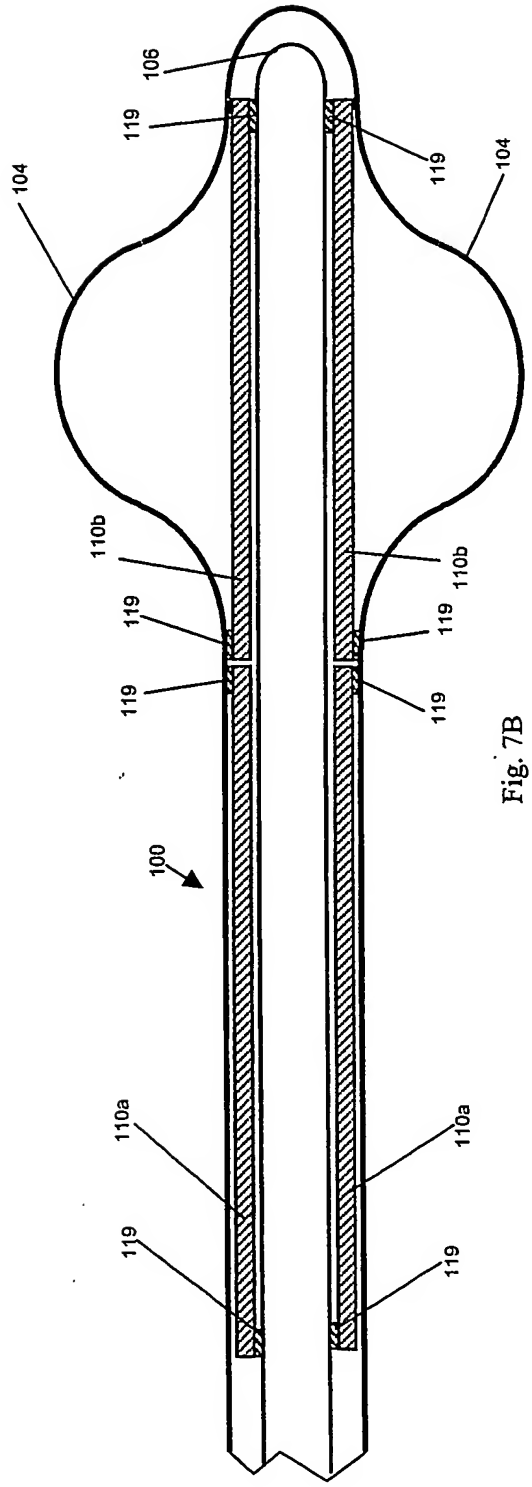

Fig. 7B

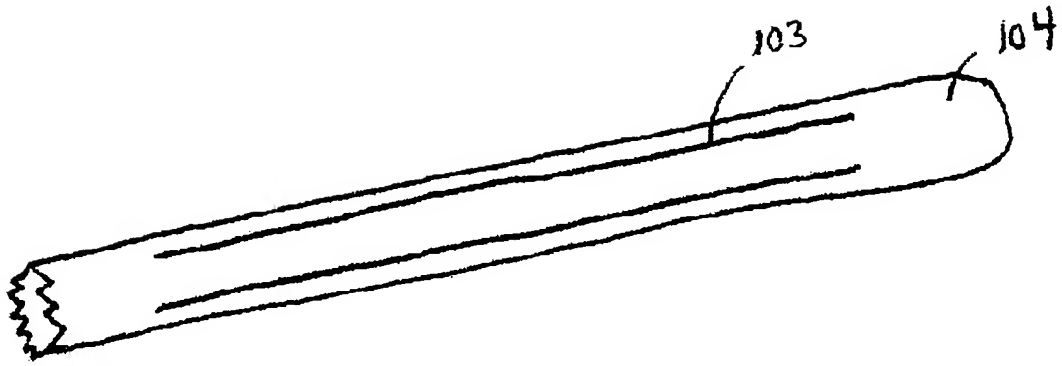

Fig. 8A

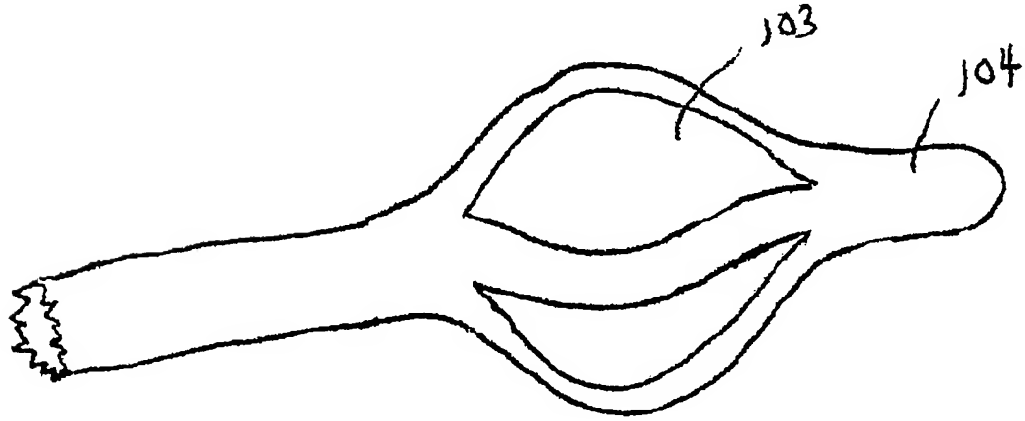

Fig. 8B

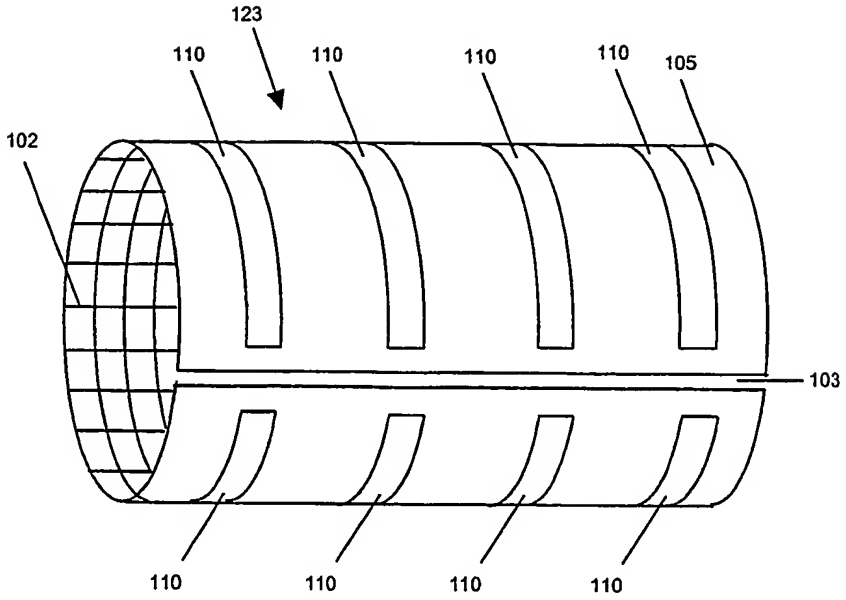

Fig. 9C

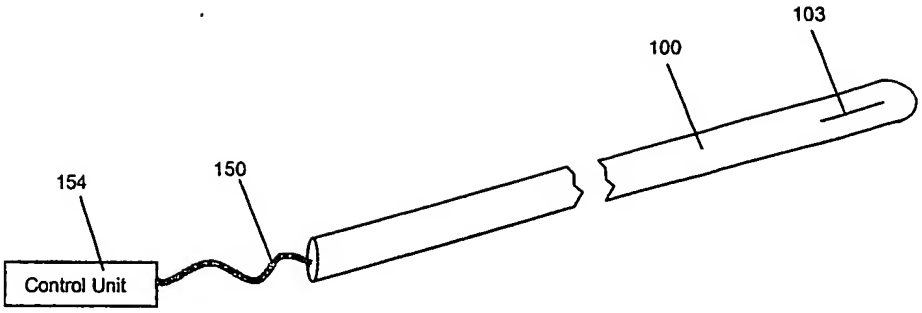

Fig. 11A

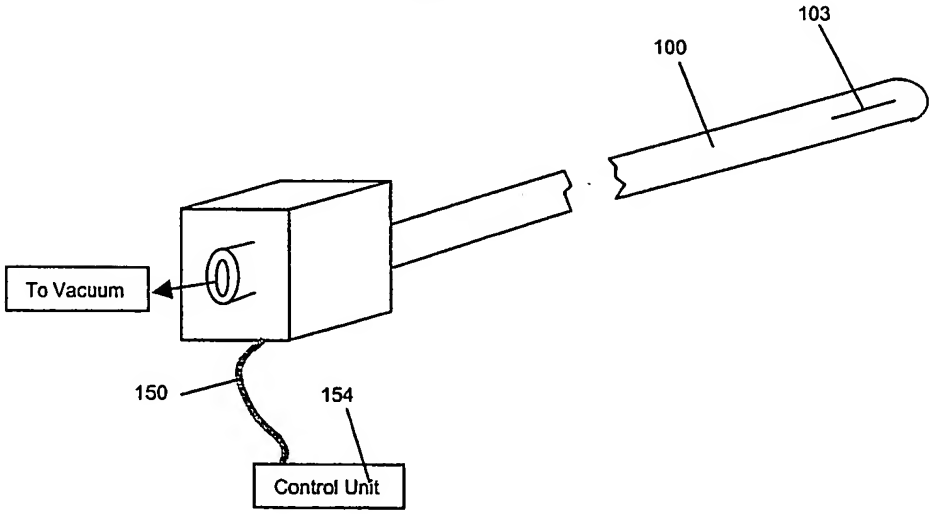

Fig. 11B

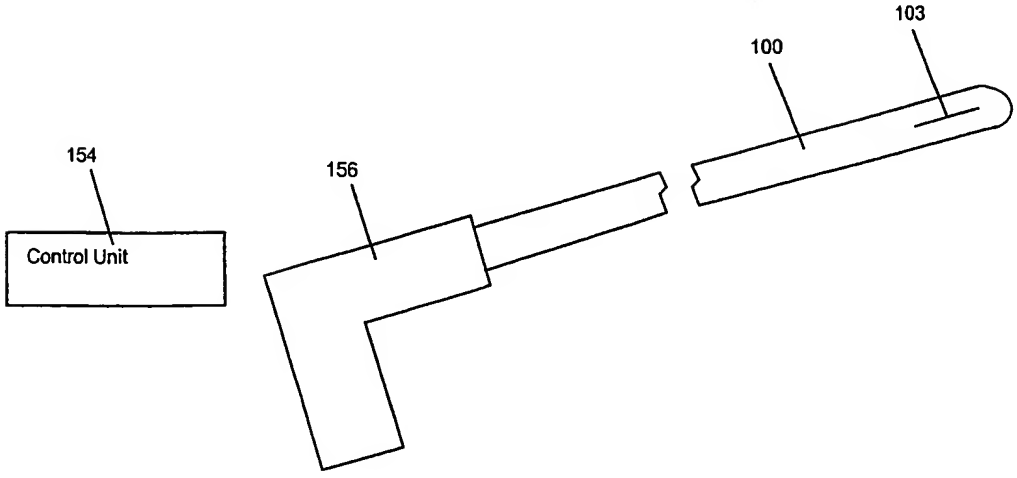

Fig. 11C

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 03/19289

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	DE 29 45 237 A (LYMBEROPOULOS) 14 May 1981 (1981-05-14) figures page 13, line 25 -page 14, line 18	1
A	US 5 372 124 A (TAKAYAMA ET AL.) 13 December 1994 (1994-12-13) figures	

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
PCT/US 03/19289

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 0078222 A	28-12-2000	SE 519023 C2	23-12-2002
		AU 5863100 A	09-01-2001
		BR 0011808 A	23-04-2002
		CA 2377368 A1	28-12-2000
		EP 1194072 A1	10-04-2002
		JP 2003502095 T	21-01-2003
		WO 0078222 A1	28-12-2000
		SE 9902348 A	22-12-2000
US 2002062062 A1	23-05-2002	US 2002022765 A1	21-02-2002
		WO 03028547 A2	10-04-2003
		US 2002120178 A1	29-08-2002
		US 2002161281 A1	31-10-2002
		US 2003032859 A1	13-02-2003
		US 2003191367 A1	09-10-2003
		AU 5129201 A	15-10-2001
		CA 2406850 A1	11-10-2001
		EP 1267701 A1	02-01-2003
		NO 20024744 A	11-11-2002
		WO 0174235 A1	11-10-2001
		US 2003004399 A1	02-01-2003
		US 2002193661 A1	19-12-2002
		US 2002193662 A1	19-12-2002
		US 2003045778 A1	06-03-2003
US 6249076 B1	19-06-2001	NONE	
DE 2945237 A	14-05-1981	DE 2945237 A1	14-05-1981
US 5372124 A	13-12-1994	JP 5208014 A	20-08-1993